



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,717	01/13/2004	Edward L. Sinofsky	CFI-5755CONT	2652
30452 7590 12/30/2009 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614				
EXAMINER SHAY, DAVID M				
ART UNIT		PAPER NUMBER		
3769				
MAIL DATE		DELIVERY MODE		
12/30/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/756,717

**Applicant(s)**

SINOFSKY, EDWARD L.

**Examiner**

david shay

**Art Unit**

3769

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on September 1, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bendarek in combination with Cox et al, Sinofsky et al (WO '722), and the admitted prior art of using saline as an irrigant. Bendarek teaches a device with an introducer sheath which is flexible, has an infusion lumen and an ablation device which is slidably positionable in multiple positions therein to perform cardiac ablation, though the preferred embodiment employs electrical energy, the equivalence of using laser energy is taught at column 6, lines 56-65. Cox et al teach a cardiac ablation device wherein the end is sufficiently flexible to be bent into a loop and teach the equivalence of endocardial and epicardial procedures for performing a MAZE procedure. Sinofsky et al (WO '722) teach the use of a connecting element as claimed (see Figure 1). It would have been obvious to the artisan of ordinary skill to employ a device and method involving forming a loop with the distal end and performing the procedure epicardially, as taught by Cox et al in the device and method of Bendarek since these are equivalents, as taught by Coz et al, or to employ the introducer sheath with the slidable ablation member and irrigation device and method of Bendarek in the device and method of Cox et al, since Cox et al teach the desirability of using laser or electrical energy for the procedure, but do not provide any specific probe configuration for these embodiments, and since the configuration of Bendarek provides more accurate positioning, and in either case to employ a connecting element as taught by Sinofsky et al (WO '722), since this will secure the device in place, even if pressure is inadvertently exerted the would otherwise deform the device's configuration, and to saline as the

irrigant, since this is a notorious irrigant and is physiologically compatible, thus producing a device and method such as claimed.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bendarek in combination with Vaska et al and the admitted prior art of using saline as an irrigant. Bendarek teaches a device with an introducer sheath which is flexible, has an infusion lumen and an ablation device which is slidably positionable in multiple positions therein to perform cardiac ablation, though the preferred embodiment employs electrical energy, the equivalence of using laser energy is taught at column 6, lines 56-65. Vaska et al teach a cardiac ablation device wherein the end is sufficiently flexible to be bent into a loop; teach the use of a connecting element at the distal end of the housing which engages the housing at a point proximal of the connecting element (see Figure 2F, element 80); and teach the equivalence of endocardial and epicardial procedures for performing a MAZE procedure. It would have been obvious to the artisan of ordinary skill to employ a device and method involving forming a loop with the distal end and performing the procedure epicardially, as taught by Vaska et al in the device and method of Bendarek since these are equivalents, as taught by Vaska et al, or to employ the introducer sheath with the slidable ablation member and irrigation device and method of Bendarek in the device and method of Vaska et al, since Vaska et al teach the desirability of using laser or electrical energy for the procedure, but do not provide any specific probe configuration for these embodiments, and since the configuration of Bendarek provides more accurate positioning, and in either case to employ saline as the irrigant, since this is a notorious irrigant and is physiologically compatible, and further to form the teather of Vaska et al as a hook, since this is not critical; is well within the scope of one having ordinary skill in the art; provides no

unexpected result; and, would allow the tip of the device to be positioned at a variety of locations along the more proximal portion of the catheter, thus producing a device and method such as claimed.

Applicant's arguments with respect to claims 1-16 and 18-30 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30

p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769